

CLOSURE FOR ROD RECEIVING ORTHOPEDIC IMPLANT
HAVING A PAIR OF SPACED APERTURES FOR REMOVAL

Cross-Reference to Related Application

This is a continuation-in-part of co-pending U.S. Patent Application, Serial No. 10/236,123 filed September 6, 2002 entitled HELICAL WOUND MECHANICALLY INTERLOCKING MATING GUIDE AND ADVANCEMENT STRUCTURE, which is now U.S. Patent No. __, __, __ and a continuation of co-pending U.S. Patent Application, Serial No. 10/014,434 filed November 9, 2001 entitled CLOSURE PLUG FOR OPEN HEADED MEDICAL IMPLANT, now Patent No. __, __, __, which was a continuation-in-part of U.S. Patent Application, Serial No. 09/732,528 entitled SET SCREW FOR MEDICAL IMPLANT WITH GRIPPING SIDE SLOTS, filed December 7, 2000, now Patent No. 6,454,772.

Background of the Invention

1 The present invention is directed to a closure for
2 operably securing a rod to an orthopedic implant wherein
3 said closure includes a break off head, a pair of removal
4 apertures for use in removal of a closure body and a
5 structure for use in interlocking together the closure and

1 the implant. The structure includes a first interlocking
2 form on the closure and a mating second interlocking form on
3 the implant. The closure is operably rotated into the
4 implant. The first and second interlocking forms are both
5 helically wound so that the first interlocking form advances
6 relative to the second interlocking form, when the closure
7 with the first interlocking form is inserted in the implant
8 and rotated. At least one of the first or second
9 interlocking forms includes a projection that overlaps and
10 radially locks with the other interlocking form when the two
11 forms are mated.

12 Medical implants present a number of problems to both
13 surgeons installing the implants and to engineers designing
14 them. It is always desirable to have an implant that is
15 strong and unlikely to fail or break during usage. It is
16 also desirable for the implant to be as small and
17 lightweight as possible so that it is less intrusive on the
18 patient. These are normally conflicting goals and often
19 difficult to resolve.

20 One particular type of implant presents special
21 problems. In particular, spinal bone screws, hooks, etc.
22 are used in many types of back surgery for repair of injury,
23 disease or congenital defect. For example, spinal bone

1 screws of this type are designed to have one end that
2 inserts threadably into a vertebra and a head at an opposite
3 end thereof. The head is designed to receive a rod or rod-
4 like member in a channel in the head. The rod is then both
5 captured in the channel and locked in the head to prevent
6 relative movement between the various elements subsequent to
7 installation.

8 There are two different major types of bone screws and
9 similar devices which are classified as closed headed and
10 open headed. While the closed headed devices are highly
11 effective at capturing and securing a rod, it is very
12 difficult during surgery to insert the rod through the
13 heads, since the rod must be introduced through an opening
14 in the head. This is because there are many bone screw
15 heads used and the rod is often curved or the heads do not
16 align. Consequently, the more screw heads that the rod must
17 pass through, the more difficult it is to manipulate the rod
18 into and through them.

19 The second type of head is an open head wherein a
20 channel is formed in the head and the rod is simply laid in
21 an open channel. The channel is then closed with a closure
22 member. The open headed bone screws and related devices are

1 much easier to use and in some situations must be used
2 instead of the closed headed devices.

3 While the open headed devices are often necessary and
4 often preferred for usage, there is a significant problem
5 associated with them. In particular, the open headed
6 devices conventionally have two upstanding arms that are on
7 opposite sides of a channel that receives the rod member.
8 The top of the channel is closed by a closure member after
9 the rod member is placed in the channel. Forces applied
10 during installation or during accidents can cause the arms
11 to splay or spread at the top which may result in failure of
12 the implant if the arms splay sufficiently to loosen or
13 release the closure. The closure can be of a slide in type,
14 but such are not easy to use. Threaded nuts are sometimes
15 used that go around the outside of the arms. Such nuts
16 prevent splaying of the arms, but nuts substantially
17 increase the size and profile of the implant which is not
18 desirable. Many open headed implants are closed by plugs
19 that screw into threads between the arms, because such have
20 a low profile. However, threaded plugs have encountered
21 problems also in that they especially produce forces that
22 are radially outward directed and that lead to splaying or
23 spreading of the arms or at least do not prevent splaying

1 due to other causes that in turn loosens or completely
2 releases the rod relative to the implant. In particular, in
3 order to lock the rod member in place, a significant force
4 must be exerted on the relatively small plug or screw. The
5 forces are required to provide enough torque to insure that
6 the rod member is clamped or locked in place relative to the
7 bone screw, so that the rod does not move axially or
8 rotationally therein. This typically requires torques on
9 the order of 100 inch-pounds.

10 Because open headed implants such as bone screws, hooks
11 and the like are relatively small, the arms that extend
12 upwardly at the head can be easily bent by radially outward
13 directed forces due to the application of substantial forces
14 required to lock the rod member. Historically, early
15 closures were simple plugs that were threaded with V-shaped
16 threads and which screwed into mating threads on the inside
17 of each of the arms. But, as noted above, conventional V-
18 shaped threaded plugs exert radially outward forces and tend
19 to splay or push the upper ends of the arms radially outward
20 upon the application of a significant amount of torque,
21 which ends up bending the arms relative to a body
22 sufficiently to allow the threads to loosen or disengage
23 from each other and the closure to loosen and/or disengage

1 from the implant and thereby fail. To counter splaying,
2 various engineering techniques were applied to allow the
3 head to resist the spreading force. For example, in one
4 attempt, the arms were significantly strengthened by
5 increasing the width of the arms a significant amount. This
6 had the unfortunate effect of substantially increasing the
7 weight and the profile of the implant, which was
8 undesirable.

9 Many prior art devices have also attempted to provide
10 outside rings or some other type of structure that goes
11 about the outside of the arms to better hold the arms in
12 place either independently or while a center plug was
13 installed and thereafter. This additional structure may
14 cause the locking strength of the plug against the rod to be
15 reduced which is undesirable, especially when additional
16 structure is partly located between the plug and the rod, as
17 is the case in some devices. Also, the additional elements
18 are unfavorable from a point of view of implants, since it
19 is typically desirable to maintain the number of parts
20 associated with the implants at a minimum and, as noted
21 above, to keep the profile, bulk and weight as minimal as
22 possible.

1 Prior designers have also attempted to resolve the
2 splaying problem by providing a closure with a pair of
3 opposed radially extending wedges or flanges that are
4 designed to twist ninety degrees and that have mating
5 structure in the arms of the implant. Such devices serve as
6 a closure and do somewhat resist splaying of the arms, but
7 are often very difficult to use. In particular, the rods
8 normally have some curvature as the rods are bent to follow
9 the curvature of the spine and normally bow relative to the
10 bottom of the bone screw channel that receives such a rod.
11 The rod thus fills much of the channel and must be "unbent"
12 to rest on the bottom of the channel or pushed toward the
13 bottom of the channel and held securely in place.
14 Therefore, the rod is preferably compressed and set by the
15 plug by advancement of the plug into the channel in order to
16 assure that the plug will securely hold the rod and that the
17 rod and plug will not loosen when post assembly forces are
18 placed on the rod. Because it takes substantial force to
19 seat the rod, it is difficult to both place the plug fully
20 in the channel and rotate the plug for locking while also
21 trying to line up wedges on the plug with the mating
22 structure. It is much easier to align the closure plug or
23 mating structure with the mating structure of the arms at

1 the top of the arms and then rotate the plug so as to
2 advance the plug in a plug receiver toward the rod. In this
3 way, the plug starts applying significant force against the
4 rod only after parts of the mating structure have at least
5 partly joined at which time torque can be applied without
6 having to worry about alignment. It is also noted that in
7 prior art plugs where wedges are used, the cross section of
8 the structure changes therealong so that the device "locks
9 up" and cannot turn further after only a small amount of
10 turning, normally ninety degrees.

11 Consequently, a lightweight and low profile closure
12 plug is desired that resists splaying or spreading of the
13 arms while not requiring significant increases in the size
14 of the screw or plug heads and not requiring additional
15 elements that encircle the arms to hold the arms in place.

16 It is noted that the tendency of the open headed bone
17 screw to splay is a result of the geometry or contour of the
18 threads typically employed in such devices and the inability
19 of threads to timely interlock with each other or a mating
20 structure. In the past, most bone screw head receptacles
21 and screw plugs have employed V-shaped threads. V-threads
22 have leading and trailing sides oriented at angles to the
23 screw axis. Thus, torque on the plug is translated to the

1 bone screw head at least partially in an axial direction,
2 tending to push or splay the arms of the bone screw head
3 outward in a radial direction. This in turn spreads the
4 arms of an internally threaded receptacle away from the
5 thread axis so as to loosen the plug in the receptacle.

6 The radial expansion problem of V-threads has been
7 recognized in various types of threaded joints. To overcome
8 this problem, so-called "buttress" threadforms were
9 developed. In a buttress thread, the trailing or thrust
10 surface is oriented perpendicular to the thread axis, while
11 the leading or clearance surface remains angled. This
12 theoretically results in a neutral radial reaction of a
13 threaded receptacle to torque on the threaded member
14 received.

15 Development of threadforms proceeded from buttress
16 threadforms which in theory have a neutral radial effect on
17 the screw receptacle to reverse angled threadforms which
18 theoretically positively draw the threads of the receptacle
19 radially inward toward the thread axis when the plug is
20 torqued. In a reverse angle threadform, the trailing side
21 of the external thread is angled toward the thread axis
22 instead of away from the thread axis, as in conventional V-
23 threads. While buttress and reverse threadforms reduce the

1 tendency to splay, the trailing and leading surfaces of such
2 a threadform are linear allowing opposing sides to slide
3 relative to the surfaces so that the arms can still be bent
4 outward by forces acting on the implant and the threads can
5 be bent by forces exerted during installation. Therefore,
6 while certain threadforms may not exert substantial radial
7 forces during installation, at most such threadforms provide
8 an interference or frictional fit and do not positively lock
9 the arms in place relative to the closure plug.

10 It is also noted that plugs of this type that use
11 threadforms are often cross threaded. That is, as the
12 surgeon tries to start the threaded plug into the threaded
13 receiver, the thread on the plug is inadvertently started in
14 the wrong turn or pass of the thread on the receiver. This
15 problem especially occurs because the parts are very small
16 and hard to handle. When cross threading occurs, the plug
17 will often screw partially into the receiver and then "lock
18 up" so that the surgeon is led to believe that the plug is
19 properly set. However, the rod is not tight and the implant
20 fails to function properly. Therefore, it is also desirable
21 to have a closure that resists crossthreading in the
22 receiver.

1 For closures of the type described herein to function
2 properly, such closures are "set" or torqued to a preferred
3 torque, often 95 to 100 inch pounds. The operating region
4 where the implants are installed is within the body and the
5 parts are relatively very small. Consequently, the closures
6 of the present invention preferably can be readily gripped
7 and torqued. In order to reduce profile, a driving or
8 installation head is designed to break away at a preselected
9 torque.

10 After the closure is installed, it is sometimes
11 necessary to remove the closure. For purposes of removal,
12 the driving head is no longer available, so structure is
13 required to allow quick easy removal and which cooperates
14 effectively with the guide and advancement structure
15 utilized with the closure.

16

17 Summary of the Invention

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19 A non threaded guide and advancement structure is
20 provided for securing a plug or closure in a receiver in an
21 orthopedic implant. The receiver is a rod receiving channel
22 in an open headed bone screw, hook or other medical implant

1 wherein the channel has an open top and is located between
2 two spaced arms of the implant.

3 The guide and advancement structure has a first part or
4 interlocking form located on the closure and a second part
5 or interlocking form that is located on the interior of the
6 receiving channel. The interlocking forms lock and resist
7 sidewise or radial movement of load bearing leading or
8 trailing surfaces rather than simply interfere with movement
9 due to placement.

10 Both parts of the guide and advancement structure are
11 spirally or more preferably helically wound and extend about
12 the closure and receiving channel for at least one complete
13 360° pass or turn. Preferably, both parts include multiple
14 turns such as 2 to 4 complete 360° rotations about the
15 helixes formed by the parts. The helixes formed by the
16 parts are coaxial with the closure when the closure is fully
17 received in or being rotated into the receiving channel
18 between the arms.

19 One major distinguishing feature of the guide and
20 advancement structure is that each of the parts include
21 elements that mechanically interlock with the opposite part
22 or mating piece as the closure is rotated and thereby
23 advanced into the receiving channel toward the bottom of the

1 channel and into engagement with a rod received in the
2 channel.

3 Each part of the guide and advancement structure
4 preferably has a generally constant and uniform cross
5 section, when viewed in any cross sectional plane fully
6 passing through the axis of rotation of the closure during
7 insertion, with such uniform cross section preferably
8 extending along substantially the entire length of the
9 interlocking form. Opposite ends of each interlocking form
10 are feathered or the like so the cross section does change
11 some at such locations, while retaining part of the overall
12 shape. In particular, the outer surfaces of each
13 interlocking form remain sufficiently uniform to allow
14 interlocking forms to be rotated together and slide
15 tangentially with respect to each other through one or more
16 complete turns of the closure relative to the receiving
17 channel. Each part may be continuous from near a bottom of
18 the closure or receiving channel to the top thereof
19 respectively. In certain circumstances one or both parts
20 may be partly discontinuous, while retaining an overall
21 helical configuration with a generally uniform cross
22 sectional shape. When the interlocking form has multiple
23 sections due to being discontinuous, each of the sections

1 has a substantially uniform cross section along
2 substantially the entire length thereof.

3 In order to provide an interlocking structure, the
4 parts of the structure include helical wound projections or
5 interlocking forms that extend radially outward from the
6 closure and radially inward from the receiving channel. The
7 interlocking forms may be of many different shapes when
8 viewed in crosssection with respect to a plane passing
9 through the axis of rotation of the plug during insertion.
10 In general, the interlocking forms increase in axial aligned
11 width or have a depression at a location spaced radially
12 outward from where the interlocking form attaches to a
13 respective closure or receiving channel, either upward (that
14 is, parallel to the axis of rotation of the closure in the
15 direction from which the closure comes or initially starts)
16 or downward or in both directions. This produces a first
17 mating element that is in the form of a protrusion, bump,
18 ridge, elevation or depression on the interlocking form that
19 has a gripping or overlapping portion. The opposite
20 interlocking form has a second mating element with a
21 gripping or overlapping portion that generally surrounds or
22 passes around at least part of the first mating element in
23 such a way that the two are radially or sideways

1 mechanically locked together when the closure is advanced
2 into the receiving channel.

3 Therefore, in accordance with the invention a mating
4 and advancement structure is provided for joining two
5 devices, that are preferably medical implants and especially
6 are an open headed implant that includes a rod receiving
7 channel and a closure for closing the receiving channel
8 after the rod is received therein. The mating and
9 advancement structure includes a pair of mateable and
10 helical wound interlocking forms with a first interlocking
11 form located on an outer surface of the closure and a second
12 interlocking form located on an inner surface of the
13 receiving channel or receiver. The first and second
14 interlocking forms are startable so as to mate and
15 thereafter rotatable relative to each other about a common
16 axis so as to provide for advancement of the closure into
17 the receiver during assembly when the closure interlocking
18 form is rotated into the receiver interlocking form. The
19 first and second interlocking forms have a helical wound
20 projection that extends radially from the closure and the
21 receiver respectively. Each interlocking form projection
22 has a base that is attached to the closure or receiver
23 respectively and preferably includes multiple turns that may

1 each be continuous or partially discontinuous with constant
2 or uniform cross-sectional shape. The interlocking forms
3 have substantial axial width near an outer end thereof that
4 prevents or resists misalignment of the interlocking form
5 during initial engagement and rotation thereof.

6 After assembly, in some embodiments each turn of each
7 projection generally snugly engages turns of the other
8 projection on either side thereof. In other embodiments
9 there must be sufficient tolerances for the parts to slide
10 tangentially, so that when thrust surfaces of the
11 interlocking forms are very close during tightening, some
12 gap occurs on the leading side of the closure interlocking
13 form. In such a case the portions of the interlocking forms
14 on the thrust side thereof lock together and prevent radial
15 splaying.

16 Located radially spaced from where the base of each
17 projection is attached to either the closure or receiver
18 respectively, is an axially extending (that is extending in
19 the direction of the axis of rotation of the plug or
20 vertically) extension or depression. The opposite or mating
21 interlocking form has elements that wrap around or into such
22 extensions or depressions of the other interlocking form.
23 That is, the forms axially interdigitate with each other and

1 block radial outward movement or expansion. In this way and
2 in combination with the interlocking forms preferably being
3 snug or close relative to each other with sufficient
4 clearance to allow rotation, the interlocking forms, once
5 assembled or mated lock to prevent radial or sideways
6 slipping or sliding relative to each other, even if forces
7 are applied that would otherwise bend the base of one or
8 both relative to the device upon which it is mounted. It is
9 possible that the cross section of the projection (in a
10 plane that passes through the plug axis of rotation of the
11 closure) of each section of each turn or pass of the
12 interlocking form be the same, although this is not required
13 in all embodiments. For example, part of the interlocking
14 form may be missing in the region between opposed arms when
15 assembly is complete as this area is not required to hold
16 the arms together.

17 Preferably, the present invention provides such an
18 interlocking form for use in a medical implant closure which
19 resists splaying tendencies of arms of a receiver. The
20 interlocking form of the present invention preferably
21 provides a compound or "non-linear" surface on a trailing
22 face, thrust face or flank of the interlocking form,

1 although the "non-linear" surface may also be placed on the
2 leading face.

3 Preferably, the interlocking form located on the
4 closure is helically wound about a cylindrical outer surface
5 of the closure and has an inner root, and an outer crest
6 that remain constant over substantially the entire length of
7 the interlocking form. The receiver has a mating or similar
8 shaped interlocking form wound about the interior thereof.
9 In this embodiment the interlocking form has leading or
10 clearance surfaces and trailing or thrust surfaces,
11 referenced to the direction of axial movement of the form
12 when rotated into one another. The structure also includes
13 an internal helical wound interlocking form located on an
14 internal surface of a receiver member and has an outer root
15 and an inner crest. The internal interlocking form has
16 thrust surfaces which are oriented in such a direction so as
17 to be engaged by the thrust surfaces of the external
18 interlocking form of a member engaged therewith.

19 In certain embodiments, the thrust surfaces are "non-
20 linear" or compound. That is, the thrust surfaces have a
21 non-linear appearance when represented in cross section.
22 The purpose for the non-linear or compound surface is to
23 provide a portion of the thrust surface which is oriented in

1 such a direction so as to resist a tendency of the receiver
2 to expand or splay when tightening torque is applied to
3 rotate the interlocking forms into a mating relationship or
4 when other forces are encountered. As applied to a closure
5 for an open headed bone implant screw, the non-linear or
6 compound surfaces of the interlocking forms whether on
7 tracking surfaces, leading surfaces or both interlock and
8 resist splaying tendencies of the arms of the head. The
9 objective of the interlocking form is not necessarily to
10 generate a radially inwardly directed force on the
11 receptacle in tightening the fastener (although this may
12 occur in some embodiments), but importantly to resist
13 outward forces generated by engagement of the closure with
14 the closure receptacle or by other forces applied to the
15 components joined by the closure and closure receptacle and
16 prevent splaying. It is noted that the present invention
17 requires that only a portion of the thrust surfaces of a
18 closure be so configured as to face toward the closure axis
19 and only a portion of thrust surfaces of a closure
20 receptacle face away from the axis.

21 In certain embodiments, an axial extension or
22 depression is located on the thrust or trailing surface, or

1 alternatively for such to be located on the opposite or
2 leading surface or both.

3 Further, in some embodiments a section of the
4 interlocking form at the crest, that is located radially
5 outward of the root, is enlarged in cross sectional area to
6 create a gripping, locking or stopping surface that resists
7 slippage or sliding in a radial direction relative to an
8 opposed interlocking form. In a complementary manner, a
9 section of the interlocking form between the root and the
10 crest which is radially spaced from the root is enlarged in
11 cross sectional area to create a gripping, locking or
12 stopping surface that engages a like surface of the opposite
13 interlocking form. The enlarged sections of the inner and
14 outer interlocking forms are created by cutting, molding,
15 machining or the like grooves or channels or the like into a
16 radially inward portion of the thrust surface of the
17 external interlocking form and mating grooves or channels
18 into a radially outward portion of the thrust surface of the
19 internal interlocking form. Such grooves or channels may be
20 formed by specially shaped taps and dies, cutting elements
21 or by other suitable manufacturing processes and
22 technologies, including molding.

1 The interlocking forms of the present invention may be
2 implemented in a variety of configurations of non-linear,
3 compound, or complex trailing and/or leading surfaces. The
4 nomenclature used to describe variations in the interlocking
5 forms of the present invention is especially referenced to
6 the external interlocking forms located on a closure, with
7 complementary, mating or similar shapes applied to the
8 internal interlocking forms on a receiver. In an axial
9 shoulder interlocking form of the present invention, a
10 somewhat squared gripping shoulder is formed near an outer
11 periphery of the external interlocking forms and an inner
12 gripping surface on the internal interlocking forms. The
13 axial shoulder interlocking form results in complementary
14 cylindrical surfaces on the external and internal
15 interlocking forms which mutually engage when the fastener
16 or closure is rotated into a closure receptacle.

17 In an axial extending bead interlocking form, the
18 external interlocking form is provided with a rounded
19 peripheral bead or lateral lip which projects in an axial
20 direction along the interlocking form crest and a
21 complementary rounded concave channel in the internal
22 interlocking form. The reverse occurs with the internal
23 interlocking form.

1 Other alternative forms include a radial bead
2 interlocking form wherein a rounded bead enlargement is
3 formed on the radially outward periphery at the crest of the
4 external interlocking form, while the internal interlocking
5 form is formed in a complementary manner to receive the
6 radial bead interlocking form. A scalloped or scooped
7 interlocking form which is, in effect, a reciprocal of the
8 axial bead interlocking form and has a rounded channel or
9 groove located along the thrust surface of the external
10 interlocking form with a complementary rounded convex bead
11 shape associated with the internal interlocking form. A
12 variation of the axial bead interlocking form is a medial
13 bead embodiment. In the medial bead interlocking form, a
14 bead projects from a base thrust surface of an external
15 interlocking form in an axial direction at a location
16 medially between the root and crest of the interlocking
17 form. In a complementary medial bead internal interlocking
18 form, an axial groove is formed in a base thrust surface
19 between the root and crest. In a medial groove interlocking
20 form, an axial groove is formed in a base thrust surface of
21 the external interlocking form medially between the root and
22 crest, while the internal interlocking form has an axial
23 bead located medially between the root and crest.

1 Variations in the above described interlocking forms
2 are envisioned with respect to relative extensions or
3 enlargements and depressions or depth of grooves of the
4 various interlocking forms. In some variations, the
5 opposite interlocking forms have the same but reversed and
6 inverted cross section, whereas in others the cross section
7 of the paired interlocking forms mates but is different. It
8 is noted that many other configurations of interlocking
9 forms with non-linear, compound or complex thrust surfaces
10 are envisioned, which would be encompassed by the present
11 invention.

12 The interlocking forms of the present invention find
13 particularly advantageous application in various types of
14 bone implant devices. The interlocking forms also have
15 advantages in reducing misalignment problems of cross-
16 interlocking and misinterlocking of interlocking forms when
17 the opposed interlocking forms are joined and rotated which
18 is commonly encountered in such devices when threads of
19 various types are used.

20 A breakoff head is provided for rotating and driving
21 the closure along the axis of the receiver. The breakoff
22 head is axially secured to the closure and breaks from the
23 remainder of the closure after the closure is set against a

1 rod and a predetermined torque is obtained, for example 100
2 inch pounds.

3 A pair of spaced apertures or bores extend from the top
4 to the bottom of a body of the closure and are fully exposed
5 by the breakoff head being broken therefrom. The bores are
6 parallel to the axis of the body and spaced from both the
7 axis and the periphery or outer surface of the body. The
8 bores are sized and positioned to receive a removal tool
9 having a pair of spaced prongs or extensions that are sized
10 to slidably fit snugly in the body apertures to provide for
11 removal of the body upon counterclockwise rotation of the
12 tool. The apertures and prongs can have any mating type
13 crosssection such as round, rectangular, crescent, kidney or
14 the like.

15

16 Objects and Advantages of the Invention

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18 Therefore, objects of the present invention include
19 providing an improved closure plug or closure top for use
20 with an open headed bone screw; providing such a closure
21 having a cylindrical base and a driving or installation head
22 that breaks away from the base at a breakaway region to
23 provide a low or minimized profile subsequent to

1 installation of the closure; providing such a closure having
2 removal structure enabling positive, non-slip engagement of
3 the closure by a removal tool; providing such a closure in
4 combination with an open headed bone implant screw for use
5 in anchoring a bone fixation structural member, such as a
6 rod; providing such a closure combination in which the open
7 headed bone screw includes a pair of spaced apart arms
8 forming a rod receiving channel; providing such a closure
9 combination including an external guide and advancement
10 flange on the closure and internal guide and mating
11 structure on inner surfaces of the bone screw head which
12 cooperate to resist tendencies of the arms to splay or
13 diverge when the closure is torqued tightly into clamping
14 engagement with a rod positioned in the channel; providing
15 such a combination including features to enhance setting
16 engagement of the closure with a rod in the bone screw
17 channel; providing such a combination in which a forward end
18 of the closure is provided with a peripheral cup point or V-
19 ring to cut into the surface of the rod when the closure is
20 securely torqued, to resist translational and rotational
21 movement of the rod relative to the bone screw; and
22 providing such an anti-splay closure plug or fastener which
23 is economical to manufacture, which is secure and efficient

1 in use, and which is particularly well adapted for its
2 intended purpose.

3 Other objects and advantages of this invention will
4 become apparent from the following description taken in
5 conjunction with the accompanying drawings wherein are set
6 forth, by way of illustration and example, certain
7 embodiments of this invention.

8 The drawings constitute a part of this specification,
9 include exemplary embodiments of the present invention, and
10 illustrate various objects and features thereof.

11

12 Brief Description of the Drawings

13

14 Fig. 1 is an enlarged perspective view of an anti-splay
15 closure with a break off driving head in accordance with the
16 present invention.

17 Fig. 2 is a side elevational view of the closure at a
18 further enlarged scale.

19 Fig. 3 is a top plan view of the closure.

20 Fig. 4 is a bottom plan view of the closure and
21 illustrates a V-ring and point on the bottom of the closure.

1 Fig. 5 is a cross sectional view of the closure, taken
2 on line 5-5 of Fig. 3 and illustrates internal details of
3 the break off head and a pair of removal apertures.

4 Fig. 6 is a fragmentary side elevational view at a
5 reduced scale of the closure in combination with an open
6 headed bone screw implant, prior to separation of the
7 breakaway head.

8 Fig. 7 is a view similar to Fig. 6 and illustrates
9 separation of the breakaway head of the closure due to
10 exceeding a preselected torque thereon.

11 Fig. 8 is an enlarged top plan view of the closure
12 within the open headed bone screw subsequent to breaking
13 away of the break off head.

14 Fig. 9 is an enlarged cross sectional view of the
15 closure of the present invention, taken along the line 5-5
16 of Fig. 3 but subsequent to installation in the bone screw
17 and illustrates details of anti-splay flange structure and
18 of the closure and mating structure of a head of the bone
19 screw, further illustrating a removal tool inserted in the
20 removal apertures for effecting removal of the closure from
21 the bone screw.

22

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1 Detailed Description of the Invention

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3 As required, detailed embodiments of the present

4 invention are disclosed herein; however, it is to be

5 understood that the disclosed embodiments are merely

6 exemplary of the invention, which may be embodied in various

7 forms. Therefore, specific structural and functional

8 details disclosed herein are not to be interpreted as

9 limiting, but merely as a basis for the claims and as a

10 representative basis for teaching one skilled in the art to

11 variously employ the present invention in virtually any

12 appropriately detailed structure.

13 Referring to the drawings in more detail, the reference

14 numeral 1 generally designates an anti-splay closure with a

15 pair of partial axial bores or apertures 2 and 3. The

16 closure 1 generally includes a closure plug or body 4 and a

17 breakaway head 6 for installation. The closure 4 is used in

18 cooperation with an open headed bone implant screw 8 (Figs.

19 6 and 7) to form an implant anchor assembly 9 to secure or

20 anchor a spinal fixation member or rod 10 with respect to a

21 bone 12, such as a vertebra.

22 The bone screw 8 includes a threaded shank 14 for

23 threadably implanting the screw 8 into the bone 12 and an

1 open head 16 having a pair of upwardly extending and spaced
2 apart arms 18 defining a U-shaped channel 20 therebetween to
3 receive the rod 10. Inner surfaces of the arms 18 have an
4 internal guide and advancement structure 22 (Fig. 8)
5 machined, tapped, or otherwise formed, therein. The head 16
6 includes grip indentations 23 (Fig. 8) to facilitate
7 gripping the bone screw 8 by an appropriate screw gripping
8 tool (not shown) during manipulation for implantation of the
9 bone screw 8 into the bone 12.

10 The closure body 4 is cylindrical in external shape
11 about a closure axis 25 (Fig. 7) and has a forward, leading,
12 or inner end 27 on the bottom and a rear, trailing, or outer
13 end 28 on the top. The breakaway head 6 is connected to the
14 body 4 at the rear end 28 by way of a weakened region
15 represented by a breakaway line or ring 30 formed by
16 selectively reducing the wall thickness of the closure 1 in
17 that region so as to weaken the region. The breakaway ring
18 30 is thinned in such a manner that it fails when a
19 preselected torque is applied to the body 4, as a result of
20 torque being applied to the head 6 by conventional socket
21 tools or the like to tighten the body 4 within the bone
22 screw 8. As illustrated, the breakaway head 6 has a
23 hexagonal outer surface 31 to facilitate non-slip engagement

1 by an installation tool (not shown). The head 6 may also be
2 provided with a set of tool slots 32 for alternative or more
3 positive non-slip engagement of the head 6 by the
4 installation tool. The head 6 has a central and axially
5 aligned bore 34 that is coaxial with the removal bores 2 and
6 3 and that defines the break off point of the head 6 in
7 conjunction with the ring 30 and ends in a chamfer 33.
8 Separation of the head 6 from the body 4, as shown in Fig.
9 7, is desirable to control or limit torque applied by the
10 body 4 to the rod 10 within the bone screw head 16,
11 preferably such that the body 4 is at or below the tops of
12 the arms 18 so as to present a low profile.

13 The body 4 is provided with a guide and advancement
14 flange 35 which coaxially extends helically about the
15 cylindrical body 4. The flange 35 is enlarged at its outer
16 periphery or radial crest to form a generally inwardly
17 facing or inward anti-splay surface 37. In a similar
18 manner, the bone screw guide and advancement structure 22
19 which are discontinuous but which matingly engage and
20 receive the body flange 35 are enlarged at their radially
21 outward peripheries or roots to form generally outwardly
22 facing or outward anti-splay surfaces 39. The anti-splay or
23 splay resisting surfaces 37 and 39 mutually engage when the

1 body 4 is advanced into the bone screw head 16 and
2 particularly when the body 4 is strongly torqued within the
3 head 16 to resist any tendency of the arms 18 to be urged
4 outwardly, or splayed, in reaction to such torque.

5 Although particular contours of the flange 35 and
6 mating structures 22 are shown herein, other contours of
7 anti-splay guide and advancement flanges 35 and mating
8 structures 22 are foreseen. Examples of such alternative
9 configurations of anti-splay or splay resisting guide and
10 advancement flange and groove structures are disclosed in U.
11 S. Patent application, Serial No. 10/236,123 which is now U.
12 S. Patent No. __, __, __, which is incorporated herein by
13 reference. The flange 35 and mating structure 22 cooperate
14 to guide and advance the body 4 into clamping engagement
15 with the rod 10 within the channel 20 in response to
16 rotation of the closure 1.

17 In order to more positively secure the rod 10 within
18 the head 16 of the bone screw 8, the closure 4 is provided
19 with penetrating structure such as a V-ring 42 and an
20 axially aligned point 43 on the inner or forward end 27
21 thereof. The V-ring 42 cuts into the surface of the rod 10
22 when the body 4 is tightly torqued into the head 16. The V-
23 ring 42 extends about a periphery of the inner end 27 of the

1 body 4 and, thus, provides two possible areas of engagement
2 between the body 4 and the rod 10, particularly if the rod
3 10 is relatively straight and acts with the point 43 to help
4 secure the rod 10 in the bone screw 8.

5 In the great majority of cases, the body 4 is torqued
6 into engagement with the rod 10 in the bone screw 8, the
7 installation head 6 is broken away, and the anchor assembly
8 9 is permanently implanted in the bone 12. However, spinal
9 alignment geometry is complex, and it is sometimes necessary
10 to make adjustments to a spinal fixation system.
11 Additionally, slippage or failure of spinal fixation
12 components can occur due to injury to the patient,
13 deterioration of bone tissue or the like. It is also
14 possible that an implant system using anchored rods might be
15 used therapeutically, for example, to set a broken bone and
16 subsequently removed. For these reasons, implant anchor
17 assemblies require a structure or mechanisms for removing an
18 anchor assembly 9 to make such adjustments or changes in a
19 spinal fixation system. The anchor assembly 9 of the
20 present invention provides retraction of the body 4 out of
21 the bone screw head 16 to release the rod 10 to reposition
22 of the rod 10 relative to the bone screw 8 or overall
23 removal of the bone screw 8 and rod 10.

1 The body 4 includes the pair of apertures or bores 2
2 and 3 which extend between the surfaces 27 and 28. The
3 bores 2 and 3 are cylindrical in shape, but may be other
4 shapes such as square, rectangular, crescent, kidney bean or
5 the like in horizontal cross section. The bores 2 and 3 are
6 spread from each other and are also spaced radially outward
7 from the axis 25 and from a radially outer surface 45, as
8 seen in Fig. 5. The bores 2 and 3 are each joined by a
9 relief 47 and 48 respectively that intersect with the bores
10 2 and 3 and open onto the intersection of the head 6 and
11 body 4 and opposite sides thereof.

12 The body 4 is removed from the bone screw head 16 by
13 insertion of a tool 55 into the bores 2 and 3, as seen in
14 Fig. 9, and then counterclockwise rotating the tool 55. In
15 particular, the tool 55 includes a handle 56 (partially
16 shown in Fig. 9) with a pair of prongs 58 and 59 that extend
17 from one end of the tool 55 and are parallel to the axis of
18 the tool handle 56. The prongs 58 and 59 are sized and
19 shaped to snugly but slidably fit into the bores 2 and 3
20 respectively. When the handle 55 is rotated
21 counterclockwise by a crossbar or other tool (not shown),
22 the body 4 rotates and backs out of the bone screw head 16,

1 so that the rod 10 can be repositioned or the bone screw 8
2 completely removed from the vertebra 12.

3 It is to be understood that while certain forms of the
4 present invention have been illustrated and described
5 herein, it is not to be limited to the specific forms or
6 arrangement of parts described and shown.

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